Clinical Laboratory COVID-19 Response Call

December 14, 2020

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JASMINE CHAITRAM: Thank you. Hey everyone. This is Jasmine Chaitram. I'm with the CDC Division of Laboratory Systems. I'm the Associate Director for Laboratory Preparedness. Thank you for joining the Clinical Laboratory COVID-19 Response Calls. We've been hosting these calls since March. The Division of Laboratory Systems has been supporting public health and clinical laboratories before COVID. We've been supporting them in areas such as quality and safety, data science, biorepository science, informatics, training and workforce development. Since the beginning of the COVID-19 response, we've been working with clinical and public health laboratories and serving as a liaison between the CDC Emergency Operations Center and the laboratory community. And providing information, hopefully, through these CLCR calls that has been relevant and useful to all of you, as well as through our Laboratory Outreach Communication System (LOCS) email messages.

Today we have a very full agenda. Before we get started, I do have a few announcements and a couple of housekeeping things that I wanted to cover. So first up, there has been a update to the point-of-care testing guidance Web page. We've added a section called “Help With Performing Point-of-Care Tests.” And this section includes CDC educational materials, documents that you can reference that help with batch testing. We also have links to training

resources from the test manufacturers for point-of-care tests. And we also have some lessons learned documents for three antigen tests, in particular, that we have either received a lot of feedback from users out there using these tests, or when CDC has been involved in studies we've noticed some key things that are important to remember when using these tests.

I really ask all of you that are out there, most of you are probably not performing point-of- care tests, but maybe you are affiliated or have colleagues or partners that are performing these tests. And we ask that you promote this page so that the information is out there and helpful to those that are performing point-of-care testing. Also updated on the CDC specimen collection guidance, our new infographics specifically, for nasopharyngeal specimen collection and nasal mid-turbinate specimen collection. These are embedded in the specimen collection guidance, hope you find these useful as well.

In addition, the Division of Laboratory Systems has recently released three new videos for personal protective equipment, PPE. Those are the Fundamentals of Donning and Doffing PPE, PPE Plus Droplet Protection – Disposable Mask, and then PPE Plus Droplet Protection - Disposable Face Masks (Removing the Gown and the Gloves Together. So check out these free training resources. I think that you'll find them useful as well. And we have our links to useful information within our slide deck. We always include this so that you have the quick reference to some of the web pages that I think are more relevant to the work that you're doing.

And we have our CDC Preparedness Portal, which is the Division of Laboratory Systems portal. It's a one-stop shop. Here you can find information about our calls. This is where we post all of our transcripts, our slides, agendas. We also post all of our previously sent LOCS messages. If you need to go back and find one and review it, they can be found here as well. Our next call will be on Monday, December 28 from 3:00 to 4:00 PM. We hope you will be able to join us. I realize that's during the holidays, but the response will continue and so will our calls. And as always, we want to hear from you, especially on training and workforce development needs. Please send those needs to LabTrainingNeeds@cdc.gov.

And then finally, I'd like to remind you how to submit a question. Please use the Q&A button in the Zoom webinar. We don't want you to submit them into the chat, we'd prefer that you send them to the Q&A section of the Zoom part of this call. And it helps us if you also include an email. We will try our best to answer the questions live, but we are not always able to answer all of the questions that are submitted, and we do try to follow up. So if you want a response to your question, the best thing to do is submit it with an email address so that we can get back to you if we're not able to answer it on the call.

We do have a full agenda today. So I'm probably going to say right up in front that I'm not sure how many questions we'll get to in the hour, but we'll do our best. And one quick thing. There was a question that came through. A partner organization asked this question, and I thought it would be helpful to talk about it very quickly here in case others were interested. The question is, “will the Department of Transportation (DOT) be considering any waivers or regulatory exceptions at all for those shipping COVID-19 specimens?” For example, any relaxed training

requirements or alternative packaging requirements. And this question will be answered by Bill Arndt, who is the biosafety SME within the Division of Laboratory Systems. Bill?

BILL ARNDT: Thanks, Jasmine. Thanks for that question. So after discussions with the DOT, they are not planning any revisions or exceptions to the guidelines that are currently in place. However, they wanted me to reinforce the point that training for Category B is significantly different than Category A. And they referenced 49 CFR 173.199, the Category B, infectious substances regulations. And specifically, what they wanted me to remind everyone was that for training for Category B, what's required is that each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section. So training requirements are not as strict as they are for Category A, and they just wanted me to reinforce that statement. If there's any additional questions, please do not hesitate to reach out to us, and we'd be happy to answer as well.

JASMINE CHAITRAM: Thanks so much, Bill. OK. So our first speaker today is Dr. Peggy Honein, and she's from the State, Tribal, Local, and Territorial support for the CDC COVID-19 emergency response. And she'll be talking about expanded screening testing guidance. Dr. Honein?

PEGGY HONEIN: Yeah. Thanks so much, Jasmine. Can we go to the next slide, please? And just thanks for the opportunity to talk with all of you about the expanded screening testing guidance that we posted first around December 1 and then updated on the 3rd to align with the new quarantine options. And this expanded screening testing guidance was really in response to the knowledge we have now that about 50% of all new infections are transmitted by people without symptoms, either before symptom onset or from people who never develop symptoms. And the goal of this is to rapidly identify people who are asymptomatic but infected and infectious, and get them into isolation to stop the silent spread of SARS-CoV-2.

The link to the guidance, if you haven't seen this, at the bottom of this slide. Next slide, please. So the guidance lays out some different groups that jurisdictions could consider. These are not listed in a priority order, but these are groups to consider because of their number of contacts. So people who have a lot of contacts are going to be more at risk for becoming infected because of that large number of contacts with other people. And also if they become infected, they're going to be at greater risk of transmitting the infection to others. These groups also include people who might be at greater risk of transmitting to someone who is at high risk for severe illness or death.

So some of the categories to consider can be workers in high-density work sites, which could be meat processing or grocery store. Government workers that interact with the public a lot such as post offices, those who reside or work in a congregate setting, like a shelter for the homeless. Students, staff, and faculty at colleges and universities as the congregate settings and social gatherings there and other events seem to pose significant risk of transmission. Teachers and staff in K-12 schools or in childcare could be considered to prevent transmission in those settings. People who have recently traveled or are planning to travel or those who have attended mass gatherings, as well as first responders and healthcare personnel.

Not to say that jurisdictions would do everyone on this list or again, this is not in order, but here are some considerations that groups can look at and consider where they want to do some expanded screening testing. And they may do this in a step-wise manner. They may decide to do some screening in a congregate setting, shelters, serving people experiencing homelessness. They may do a round of screening and not find any cases, and that information would inform whether or not they would continue screening. Next slide, please.

So just to mention some of the broad categories of tests out there, including the nucleic acid amplification tests and there are exceptions. Some are rapid in each category, some are not. But in general, the NAAT tests are taking 24 to 48 hours for results with some exceptions. The antigen tests have mostly fallen in the category of point-of-care with results in 15 to 30 minutes. More data being developed all the time to better understand, but with the antigen tests right now and using them in asymptomatic persons, they're depending on the level of community transmission.

You may want to consider confirmatory testing for asymptomatic positives. Symptomatic people who test negative would be important to do confirmatory testing. And then just having your decisions about whether or not you do confirmatory testing informed by the pretest probability. And we have posted in the last week the interim guidance for antigen tests at the link here, which gives more of the flowcharts of how to consider in different settings and the interpretation for different results. Next slide, please.

So we provide in the guidance some community indicators to help inform the frequency and the scope of testing. So those community indicators are aligned with our dynamic indicators for school reopening as well as the indicators in the governors' reports. And really look at the incidence over the last week and the test positivity over the last week. Right now, about 95% of counties are in this highest level for incidence. It's not quite as high for the percent positivity right now, but considerable concern which informs then, for these groups that you decide to target, for some expanded screening testing guidance how frequently you would do it.

So at this highest level of transmission, really consideration should be given for as frequent as twice a week testing of these targeted groups. We look forward to a point when we're at much lower transmission, and if we get down in the green category we could really focus on enhancing screening of all the contacts, known close contacts, as well as contacts of contacts. But right now, we're more at the phase of taking a group that has a lot of contacts, risk for outbreaks and explosive transmission and doing frequent screening testing to interrupt that silent transmission. Next slide, please.

So a positive test, whether it's from an antigen test or a NAAT test, really needs to result in rapid actions, including same day notification to the health department, following up with the person tested to let them know they should keep monitoring themselves for symptoms and when they might want to seek care if they have worrying signs or symptoms. That they should immediately isolate for at least 10 days and, when feasible, to initiate contact tracing to identify

their close contacts. But also encourage the person identified to notify their household contacts that they may be at risk and should quarantine and seek testing. Next slide, please.

Important to remember is, expanded screening testing is one additional tool to try and interrupt transmission, but it should happen in the context of all of the other principal mitigation measures. So messaging about the importance of all these prevention efforts, universal use of face mask, maintaining physical distance, engineering controls when possible, such as structural barriers and Plexiglas or things that help prevent droplets spread, potentially incentives to increase compliance with quarantine and isolation, and cleaning, sanitation, and hand hygiene. And next slide.

So just want to put this in the context of really all of the actions that we can take now to slow the spread of COVID-19. If we do all of these things together, we can save lives, we can move more quickly to economic recovery, and we can also restore the community life with the full range of everyday activities that we want to do. Important in this is universal face masks wearing, maintaining that physical distance between people when possible, avoiding social gatherings. That means non-essential indoor spaces, as well as gatherings outdoors where physical distance can't be maintained, and rapidly identifying and isolating cases that we can do with the expanded screening testing guidance.

We are all delighted to see vaccine rolling out the door this weekend and immunizations starting today. This is a great step forward, but we have to do all of these things. The vaccinate widely alone is not going to interrupt transmission and control this pandemic, we need to do all of these together. So this expanded screening testing can be one tool where there is adequate screening and testing capacity in your jurisdiction to help interrupt this transmission. So that's all I have today. And happy to stick around for questions.

JASMINE CHAITRAM: Thank you so much, Dr. Honein. We do have a couple of questions that have come through. I'm going to ask you a few of them. The first one is which priority group would you use for laboratorians who did not have contact with COVID-19 related infectious material?

PEGGY HONEIN: Muted, sorry. Yeah, sorry. I clicked the wrong button. Thank you, Jasmine. If laboratorians don't have contact with COVID-19 infectious material, they're probably not going to be a high risk target group for prioritizing for expanded screening testing. We really want to be prioritizing screening testing of asymptomatic individuals that are at higher risk of infection based on their occupational setting or their residential setting. So it's unlikely that that would be a priority group, but jurisdiction should be considering and making decisions based on the risk and all the information they have available to them in their jurisdiction.

JASMINE CHAITRAM: Great, thank you. The next one is from Bill Noshowitz. It says thank you for this topic. The guidance seems centered on defined congregate settings. Does asymptomatic testing extend to include testing of these asymptomatic personnel in hospital

drive-in clinics or limit testing of these personnel within the congregate setting location itself or public health lab settings?

PEGGY HONEIN: You know, this can be done in a number of ways. And one example there is in the expanded screening testing that's going on in a number of colleges and universities that have done entry testing as well as sometimes frequent testing of twice a week throughout the semester. And that frequent testing really seems to help to control transmission in that setting, but there's also a recognition that congregate setting is intertwined with the community. So there have been some efforts to expand screening testing to not just the universities, but also the community around it.

So I think that would be the analogous situation to consider for any of these groups you might prioritize for screening testing. Is there a community that you should be screening as well, because the risk of transmission is not going to be interrupted without that. So for example, it could be not only screening testing and workers in a high density work setting like meat and poultry processing, but also considering offering that screening testing and multi-generational homes where many of those workers live and where there could also be transmission. So it is interconnected. And I think you can consider expanding beyond the immediate occupational and residential setting if you have testing capacity.

JASMINE CHAITRAM: OK. Great, thank you. The next question is, who is the intended audience for this guidance?

PEGGY HONEIN: This guidance is really directed to health departments to help them consider use of screening testing capacity that they have in a targeted way to most effectively interrupt transmission.

JASMINE CHAITRAM: OK. Thanks so much. Appreciate all of your presentation this morning, this afternoon. I don't know what time it is. And answering the questions. We did have a few more, I'll probably send those to you offline just so that we can move to our next speaker.

PEGGY HONEIN: Sounds good. Thanks for the opportunity.

JASMINE CHAITRAM: Thanks again. OK. So our next speaker today is going to be Dr. Marcus Plescia from the Association of State and Territorial Health Officials known as ASTHO, and he'll be talking about the BinaxNOW COVID-19 rapid antigen test utilization rapid query.

MARCUS PLESCIA: Great. Thank you. Thanks for having me this afternoon. So let me just give you a little bit of background about what I'm going to go over with all of you. I think everybody remembers BinaxNOW was a big initiative of the department to try to make testing more available to states and communities. And they entered into an agreement with Abbott to purchase these tests and they promised states they would be providing 100 million BinaxNOW tests across states for free. And this all, I think, happened maybe about six, seven weeks ago. So a couple of just broad comments. Early on when this occurred, I think there was a lot of

confusion and concern from states. They really weren't clear or comfortable with how they would play this role, and I think that now, almost a couple of months later, there's a lot more comfort and understanding from states on how they might go about expanding access to testing in different settings.

So what I'm going to do, with this presentation I'm going to show you some slides. This is from a survey we did of states quite some time ago, probably four or five weeks ago, early in the process when they were trying to decide how they wanted to use this extra capacity and how they would roll it out. And then I'll do a little bit of a catch up of where we think we are now. But I think the basic data that we collected back towards the beginning of November is useful because it'll give you a sense of where states really feel like some additional capacity is needed, and that's why they were trying to allocate the test in that manner. So if I could have the next slide.

So there's not a lot in this slide that really matters other than this is a survey that we did when states were actually doing their planning of how they might want to use additional testing capacity if they had additional testing capacity. And we got responses back from 30 states. Next slide. So this slide we asked, there's going to be three questions I'm going to go over here. One is in what kind of ways would you use the antigen tests, the next question is going to be in what settings, and the third is how they would prioritize them.

So when we asked about use of antigen test, what you'll see here is that about 3/4 of states are definitely going to use these tests for symptomatic individuals. And that was consistent at the time, and I think this still holds true that the EUA that the FDA did for BinaxNOW, at least initially, was specific to diagnostic testing and symptomatic individuals. And it was really the Department that decided that they could also be used in settings where there were asymptomatic individuals or for screening.

But so you see here, most states felt the additional testing capacity would be helpful in those settings. But about 1/2 of states were going to use them for symptomatic individuals, but were also going to use them in other settings. And you'll see about 1/2 the states stated there would be some situations where they might want to try to use these tests for screening asymptomatic individuals, and then it's just coincidence that the numbers, these are not related. So about 1/2 the states saw the need or potential capacity to use the BinaxNOW test for outbreak investigations or response. And then a few thought they might have some opportunity to use these for surveillance. Next slide.

These are the populations or settings that states were listed in their plans as areas that they would like to try to augment capacity in some of these settings and put these tests into use in these settings. And I think it's nice, because this does parallel, I think, quite well with the presentation that Peggy just showed you. As you can see, K-12 schools-- that keep in mind that the administration very much wanted states to use these BinaxNOW tests in K-12. And initially, they were trying to just work with the school systems in the states and not really even deal with

the state public health department or the governor's office, but I think as they delved into that they realized they kind of had to.

So in some ways states may have been indicating K-12 because that was sort of the desired response or the desired area that the department had made clear they wanted to see the tests, or they were hoping that the states would use the tests in. So most states were going to try to see if they could roll BinaxNOW testing out in states. Long term care facilities, I think that's fairly obvious because there's such a significant need for testing in long term care facilities. Federally qualified health centers and then further down the list, tribal clinics. So in the end, that is where a lot of these tests went. And they went to those settings for diagnostic testing use. Colleges and universities, Peggy sort of mentioned that. And then you'll see some other congregate settings that again, I think parallels nicely with Peggy's presentation, correctional facilities, congregate work settings, some of first responders. So these were the kinds of areas that states were looking at as far as targeting certain populations. The next slide, please.

And this is how they prioritized, how they wanted to use this. This is a little confusing to me. I usually think the higher priority would be the larger number, but 1 is the highest priority, and 5 or 6 is the lowest priority. So again, K-12, long term care facilities, the list really comes pretty close to mirroring the list I just showed you of the settings that they were identifying where they thought the test might be useful. And then the next slide, please.

OK. And so now I'm going to just segue to finish out some of the things we asked states about. And then I'll jump back and talk to you a little bit about what really happened and what some of the challenges were in trying to implement in those settings. So one of the things states were very, very concerned about reporting with these new tests, because there were so many. And they were going to be in these settings where it might be hard to get reporting. And so we wondered if states might be sort of moving towards where they might give up on trying to collect negative results, but that was not the case at the time of this survey. So states were really still wanting to get both positive and negative results back, and they were really going to push for that with the BinaxNOW tests. Next slide, please.

OK. So you can go back to the one you were just on. And let me just, so this is the survey that we did. And let me just give you a little bit of an update on kind of what's happened in states since then. All of the states were really trying to make this new modality work. I think we're appreciative of the interest in trying to just improve capacity to be able to do the testing in the state levels. But they ran into some pretty significant challenges. And probably the biggest one you saw in the slides, that everybody really did want to try to use these in school settings, but I would say that there has been very limited success in those settings. And the issue has been that there really isn't a lot of workforce capacity in school settings of somebody who states felt would really be capable of administering the test.

There are some states that have pretty robust school health nursing programs, and clearly in those states and in those communities I think you'd have better luck rolling something out like this. But most states and communities don't have very significant school health nursing

programs. And so the actual challenge of administering the tests proved to be a pretty significant issue for states who wanted to do this. Sort of staffing and capacity to do this in these settings that health departments just didn't have a very significant workforce footprint in. Another issue that states were very concerned about was ongoing access to the tests.

So the department promised 100 million tests, but there was a lot of concern. Well, we'll use 100 million tests pretty quickly. And then are there more tests that are going to be made. And I think people did feel that would be true, but then there was also a lot of concern about what would the cost be for the test and would it become prohibitive for states because the cost was so high. And this mirrored some of the early challenges that states have had with the reagents for the earlier tests which used machines, but you had to use reagents in the machines and the reagents start to get very expensive and mad it very difficult to continue using those in a wide range of settings, including long term care facilities.

So those were and continue to be the big issues that have challenged states as far as rolling these tests out in the settings that I mentioned. Use in K-12 has not been substantial so far, and actually we were just on a call with the association that represents medical directors in long term care facilities, so they have a pretty good sense of what's going on across long term care facilities. And they said that the BinaxNOW really are not being used in those situations either. They're still using the Quidel and the Abbott based testing that's based on doing the testing in an onsite machine.

So what's happened with BinaxNOW, I suspect you all are aware of this, but there ended up being some manufacturing issues or shortages. Some with the test reagents, some with the needed equipment in order to manufacture the tests. The states got a shipment of BinaxNOW, and then they didn't get any more for a while. And I think that has gotten worked out and the tests are starting to roll back out to states. This didn't help a lot with their confidence about that earlier concern about whether they would continue to have access to the tests.

And then there was another issue that the administration took issue with how eight states, I think it was, were actually implementing their BinaxNOW program. And so those states kind of got put on pause, to use the Department's wording. And I think they've worked out some of those issues, and now there's only four states that are still on pause. So the tests are starting to roll back out. It does appear that states can continue to, now that the manufacturing issues have been resolved, states will be able to continue to order these tests on their own from the manufacturer going forward if they want to continue with that.

So that's a little bit of an overview of some of the areas that states wanted to use BinaxNOW, which I think is consistent with some of the areas that states really would like to be able to expand testing. And then what our experience has been so far with the rollout of the tests. And I'm sorry, we have not surveyed the test. We have not surveyed the states recently. I'd love to have shown you a little more recent information about what people are doing. But most of what I've reported back has been more anecdotal just from occasional conversations we've had about BinaxNOW on some of the-- we have biweekly calls with our members, and so this comes

up from time to time. So that sums up the information that we have about the BinaxNOW experience in state public health forum.

JASMINE CHAITRAM: Thank you very much, Dr. Plescia. I did get a couple of questions for you. The first one is why was the Binax chosen as opposed to other rapid tests for this effort?

MARCUS PLESCIA: That was a decision of the DHHS. I don't know. I mean, I think it was that they were excited about BinaxNOW because it was one of the first tests that came out that was more an all in one kit, so the ease of doing the testing was improved. And then I guess the administration was able to reach some kind of agreement without it to contract with them for the tests. But we were just presented with the option to have access to some of these tests before it.

JASMINE CHAITRAM: OK. And the next one is we received a few boxes of these but we have not validated them. To my knowledge, we did not order them. Can I donate them to other facilities in need as we currently have ample supply of the Sofia antigen test?

MARCUS PLESCIA: So let me say one thing first. I mean, the Department of Health and Human Services, and this was mostly coming through the Office of the Assistant Secretary of Health, Admiral Giroir. They were unhappy with states when they did things that weren't sort of consistent with how they wanted the tests. So you might want to check with them before you would actually give the tests away, say to another state. What you might want to consider doing, I think that the states that probably had the best success with these where they really were useful were the states that used them in the settings that were pretty straightforward and tried and true.

Now, that didn't accomplish the interest in really improving capacity so that states could do testing in new environments where we hadn't been testing, but I would say that a lot of states found that when they offered these tests to federally qualified health centers, tribal clinics, other clinical providers who serve under-served populations, they were happy to have them and I think they put them to good use, and they use them in a diagnostic kind of way. So if you're looking within your own state of places that maybe you could roll these out into or distribute these to, that's where I would suggest. Talk to your FQHCs, or if you have FQHC networks you might try working through them.

JASMINE CHAITRAM: OK. Thank you again, Dr. Plescia for joining us today. Our next topic is the HHS diagnostics data platform, and we've actually got a few individuals that will present this information. I think we're going to start with Kristen Honey and then Nick Ipiotis and then John Wiley. So I think Kristen will kick us off.

KRISTEN HONEY: Fun. Thanks so much. Kristen Honey, and a Senior Advisor to the Assistant Secretary for Health, Admiral Brett Giroir. And this project is a relatively new effort over the past, I guess about a month we've been working on this. And truly a team effort. Very, very collaborative, so you'll hear from three of teammates on this. Next slide, please.

We're basically trying to increase the accuracy and the quantity and quality of antigen reporting. We began with BinaxNOW, and it pretty much is by any means necessary. And this means we have an interdisciplinary team that is spanning all of HHS, CDC, FDA, some members of the White House and coronavirus task force to pull our resources together and figure out what can we do to move the needle on this problem. And with that, I'll turn it over to Nick to say a few words before John walks us through the slides and the details of the whole thing. And this effort is jointly led between OASH, the Office of the Assistant Secretary for Health, under the direction of Admiral Brett Giroir. And then in close connection with the Office of the Chief Information Officer, or the HHS CIO. So Nick is the counterpart in OCIO, the Chief Information Officer, while I'm OASH. So Nick, do you want to just say a few words and then John will walk us through the slides?

NICK IPIOTIS: Absolutely. Hi, this is Nicholas Ipiotis. I'm working for the Office of the CIO at HHS. We started working actually with Abbott very early on in the process, hoping that we're going to see a lot of the results flowing through to us. But many of them, and I think Abbott is still working with the application to improve it a little bit, including the part that they can report directly to the states for the requirements. But so far, we haven't seen so many of these coming directly from Abbott. We see many of these tests coming through the similar feeds that we get at HHS. And sometimes it's difficult to separate from the other tests based on the markings, but for the most part we see the use that are happening a lot more.

JOHN WILEY: Yeah. Thanks, Nick. And so the real challenge that we're tracking down here is related to what Marcus was saying. That there are a lot of challenges with the point-of-care tests, particularly with locations that aren't used to administering them and in particular reporting them. And so we've noticed that despite the millions that have gone out, the number of reported results that are coming back through to HHS are much lower than expected. And that's for a number of reasons. Some states aren't sending the results, others are just sending the positive results. And in a lot of cases the points of care, say a K-12 school doesn't have the right technology or reporting capability. And so this lack of visibility, as we all know, can lead to a lot of challenges, especially as the administrators are trying to conduct contract tracing or decide where to distribute additional testing supplies and identify hot spots.

So our effort here is to really increase this reporting. Can we go to the next slide? And so as we were thinking about how to approach this, our first step really is to document the testing ecosystem and understand along that journey of tests and test reporting how that journey is occurring and where the bottlenecks might be. And establishing scorecards that will help us better understand where we're moving the needle and where we need to focus more.

The third is the diagnostic design-a-thon, which is really focused on bringing together as many participants in our community to develop technologies that might help. I should say grease the treads for areas where it might be more difficult right now, for instance the K-12. Maybe there's a specific type of app that might be more suitable for users in K-12, versus say, a nursing home, or a prison, for instance. And so these first three efforts really will lead us to items four and five, which will help us to increase the number of test results that are flowing through, and

importantly to estimate the positive test positivity rate from each of these sources. Can we move to the next page?

So what you're seeing here is a very high-level flow, and it gives a sense of the various work streams that are underway to help move the ball forward here. On towards the left, you're seeing all the antigen test manufacturers, and the goal here is really to just understand the overall reporting ecosystem, how the tests are flowing through to the states, and increase the visibility of what's been distributed, what is in inventory, and how it's being utilized. And then we're also working with those points of care as well as those distribution centers of the states to help increase the reporting that's happening. And that will be done through a number of different methods, both through existing technologies that could already deploy, but also others that may come out of, for instance, the design-a-thon, where we can really fill the gaps in the reporting.

And so developing that infrastructure is something we're really thinking about, how do we implement a strategy there. And then lastly is really thinking through the analytics required to provide the transparency for the federal agencies to respond to the pandemic. So I think I'll stop there. The overall thrust here is to let you know in the audience here is that this effort is ongoing, and many of you may have already been involved in conversations. We know that the antigen tests aren't necessarily what this group is focused on wholly, but you may be pulled into conversations as this project evolves. So I'll stop there and open it to Nick or Kristen, if you want to fill in any gaps, or we can open up to questions.

KRISTEN HONEY: Thanks, John. That was great, why don't we move on to questions.

JASMINE CHAITRAM: OK. So Thanks so much to the three of you for being on the call and presenting this information. I think it is useful for the laboratorians on the phone to know how the data is being used by the federal government. I appreciate that. I've got two more topics on the agenda that I want to make sure we have time for. So I'm going to go ahead and move forward in the agenda and then come back at the end if we have time for additional questions. So apologize for that, but it was a full list today. Our next topic-- Thank you. Our next topic is about managing laboratory supply shortage issues. And Dr. Michael Iademarco is currently serving in the CDC COVID-19 Testing and Diagnostics Task Force and he will say a few words about his team and the role there. Dr. Iademarco?

MICHAEL IADEMARCO: Thank you, Jasmine. How's my sound?

JASMINE CHAITRAM: You sound great. Thank you.

MICHAEL IADEMARCO: OK. Thank you. First of all, Marcus did a good job of kind of introducing this, and I think there could be some opportunity to have direct back and forth on future calls, if that's desirable. But as introduced, I'm Michael Iademarco. And I'm deployed to the Joint Coordination Cell's Testing and Diagnostic Work Group. And this group aims to coordinate test availability with those conducting tests, looking for gaps and trying to fill them. We work very

closely with other federal partners such as CDC's COVID-19 response Laboratory and Testing Task Force, people hosting this call. CDC's Health Systems and Worker Safety Task Force, the FDA and the EUA process, the Biomedical Advanced Research and Development Authority or BARDA, within ESPR, NIH's Rapid Acceleration Diagnostics Initiative, known as RADx, and very importantly, the people behind the scenes doing all this logistics work is the Air Force.

And so these groups, we try to intersect and coordinate among these groups. And we depend heavily on state and local health partners and several other healthcare organizations, universities, and clinical partners. So just briefly in three areas, or three lanes, we do our work in three ways. First, we monitor test supply manufacturing and distribution by analyzing proprietary industry-supplied data supplemented with regular two-way conversations. Second, we identify gaps in the supply chain and we attempt to influence others to close those gaps, and in select situations, we make targeted investments in expanding the industrial base. And third, related to COVID, we distribute swabs and viral transport media to states and tests-- principally point-of-care tests-- and as Marcus was explaining, the BinaxNOW test-- directly to nursing homes, assisted living facilities and other vulnerable in congregate settings.

And, I don't remember Marcus, if you mentioned the exact number, but the US government purchased 150 million tests as the sole exclusive supply coming off the conveyor belt. And those deliveries to the groups I mentioned, including state allocations, are nearing a close probably in the first week of January. And we're developing plans now for how to go forward. We think that for the BinaxNOW test there will be probably a continuation for the vulnerable with nursing homes and assisted living. And then we're looking at trying to work with the General Services Administration (GSA) schedule administered through the Department of Veterans Affairs (VA). That part of it to make tests available through states. And then the remainder going on to the open market, and we're still in negotiations with Abbott to try to figure-- [AUDIO OUT]

--test on the market, as one questioner noted in the chat. And I think there's even more coming on board. So I'll leave it at that. There's a lot of complexity. I just wanted to introduce myself. I'm new to this group, only having been here for five weeks, taking over for Dr. Tammy Beckham. And I welcome any structured engagement that CDC might organize in these types of calls in the future. Over.

JASMINE CHAITRAM: Thank you so much, Dr. Iademarco. We don't really have any questions for you. There was one comment, I'm not sure-- or I guess it's a question. I'm not sure that you can really respond to it, given that you've only been there for a few weeks. But the question was how does the supply chain look today versus six months ago? I don't know if you want to comment.

MICHAEL IADEMARCO: Yeah I think that testing, the amount of tests being done from a lab based perspective is somewhere between 1.5 and 2 million tests per day. And it's hard to estimate, actually, how many point-of-care tests are being done. But if we analyze what's being manufactured and assume they're getting done with the right lag time, it could be somewhere

between 3 and 4 million tests per day are being done. And the most important question, and we want to hear from people, with data driven analysis is how many tests do we need? The opinions at the moment are that we need more tests.

Now, to do that, that gets back to the supply chain. And there are definite issues with the supply chain. Marcus referred to one issue that ended up really focusing on specialized swabs. We have investments coming up that will address that, but industrial based expansion takes time. And we have our eyes on other things around nitrocellulose paper, injectable plastic, and a long laundry list of other supplies. So that is testing and expand we're doing our best to monitor those things and make investments. And if people have specific data-driven information, not necessarily anecdotes, it can help and feed our analysis. Over.

JASMINE CHAITRAM: OK, great. Thank you so much. We're going to move to our last topic on the agenda, because I think there are some important updates that CMS has for us. Before we do that though, I would ask for John, Kristen or Nick, somebody to put in the chat a link to the design-a-thon. We've had some requests come through in the Q&A box for a link to that, the information about the design-a-thon. So if one of you could put the link in the chat or respond to the question directly in the Q&A with the link, that would be great so everyone could see it. Amy Zale from the Centers for Medicare & Medicaid Services (CMS) has been on this phone call before with us and she's back to give us some updates on some enforcement discretion guidance that has recently come out from CMS. Amy?

AMY ZALE: Thanks, Jasmine. And thanks for the opportunity to come back and talk with everyone again. Jasmine had reached out, there are a couple of things that are out recently from CMS that she asked me to touch on and make sure that everybody was aware of. The first one is the most recent enforcement discretion that we have put out, and it's coming in response to (interestingly, because of the conversation we're having today) the BinaxNOW. And we recognize especially as it relates to assisted living facilities and trying to get that testing out there but also make sure that facilities are CLIA-certified. And so if a facility that is putting in an application for a CLIA Certificate of Waiver in order to conduct SARS-CoV-2 testing. Once they have submitted their CMS-116, that application, to their state agency, they are able to begin testing and reporting results for that specific point-of-care test.

I just want to make sure that everybody is aware that it is only for a Certificate of Waiver of laboratories and only for a point-of-care COVID-19 testing. So that's the first enforcement discretion that I was going to talk about today. The second one isn't necessarily enforcement discretion, but we've been getting a lot of questions about it. And I know that CDC has been getting a lot of questions about it as well. And it's the topic of expired reagents and expired kits. And so we just wanted to let everybody know that we put out an FAQ, and in that document we talked about can a laboratory use an expired viral RNA mini kit or swabs.

And so we just wanted to let everybody know that those specific examples were just examples for the FAQ, but what we are saying is that during the COVID-19 public health emergency, in order to address the concern over reagent and swap supply problems, which is perfect for the

conversation that was right before ours. CMS will allow laboratories to use expired COVID-19 test kits, reagents, and swabs. And what we are saying specifically is that laboratories have to have policies and procedures in place to ensure that quality control testing is happening, that the quality control is passing before they use any of those expired reagents.

And then the last thing that has come up is that we have put out an updated FAQ regarding molecular antigen point-of-care test enforcement discretion. And this revolves specifically around asymptomatic testing. We had initially had an FAQ out that was specific to point-of-care antigen testing for Certificate of Waiver laboratories, and we've expanded this enforcement discretion. So now, instead of just being a point-of-care antigen testing, it's SARS-CoV-2 molecular, and antigen tests that are authorized under EUA for point-of-care or patient care settings.

So it also was initially for a Certificate of Waiver of laboratories only, and we are expanding that to any certificate. And so any point-of-care test, whether it be antigen or molecular, in addition to whether a Certificate of Waiver laboratory or another certificate type, will not be cited for performing testing on asymptomatic patients. I know we're running close on time, so I'm happy to answer questions, but those are the three FAQs and enforcement discretion policy changes that we wanted to make sure that everybody was aware of.

JASMINE CHAITRAM: Thanks so much, Amy. There were a couple of questions for you. Is there a limit on the expiration date on reagents test kits swabs?

AMY ZALE: We are not that prescriptive. We are simply saying that if a laboratory or facility wants to be able to use those expired reagents that they need to have policies and procedures in place to ensure the proper functioning of that test kit, reagent, swab, et cetera.

JASMINE CHAITRAM: Great. And there were some questions about IQCP for EUA tests. Can you make any comments on that?

AMY ZALE: I can ask for your patience. We have something that has just come through clearance and we are waiting for final approval to get it posted. So I would say the next time you have one of these, Jasmine, I'll have an update on IQCP as they relate to EUAs.

JASMINE CHAITRAM: OK. Great, thank you so much. Dr. Iademarco, you're still on. And there is a question or comment about what the federal government is doing in regards to the current shortage of pipette tips for molecular testing. Can you comment on that?

MICHAEL IADEMARCO: Yes. So there's a lot of different types of pipette tips, and I won't go through those. So it's not just one thing, it's all different types of things. We're doing our best to track all the different types of tips. Classic example of where it's not the tips that are short necessarily, it depends, but it's the plastic that might be short, or the filters that go into certain types of the tips. So we are-- why is that situation and we think there are [AUDIO OUT]

investments to be made in the industrial base to make tips more available. And we have made some partial investments in those areas.

But through reassessment in the last month, we think there's additional needs to make investments. And after we make these investments it can take months to ramp those up. So we're aware of the shortage and the constriction. It's more than just one type of tip; it's complicated. And in order to expand the availability of "tips," quote unquote, there's multiple place and places in the industrial base to be invested. Then you also have the resources to do it. And so there were some existing resources through supplemental funding that can be and are being applied. But to fully address the problem, we think it's going to take additional funding. And we're in the process of making those needs known. Over.

JASMINE CHAITRAM: OK. Thank you very much. We're at the end of our agenda and end of time for this call today. I do want to thank all of our speakers for joining us and providing very useful information. There were a lot of questions that we weren't able to answer. We will try to get those answered and respond to them, either by email or on the next call. I do want to take this time to remind you that the next call will be on December 28 at 3:00 PM. And I also want to take this time to wish you all a very happy holiday and I hope that you all, you and your families, are well and that you stay safe, and that you will join us again on December 28. Thank you, again, for being here with us today.